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Original paper

Effect of vascular access strategy on long-term outcomes in patients with out-of-hospital cardiac arrest: a randomised clinical trial

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Abstract

Objective: The Intravenous versus Intraosseous Vascular Access for Out-of-Hospital Cardiac Arrest (IVIO) trial was a randomised clinical trial that investigated initial vascular access strategy for out-of-hospital cardiac arrest. The current manuscript presents outcomes at 6 months and 1 year.

Methods: Adults with non-traumatic out-of-hospital cardiac arrest, in whom vascular access was indicated, were randomised to initial intraosseous or intravenous access. The allocated method was attempted up to two times. Prespecified 6-months and 1-year outcomes included survival, survival with a favourable neurological outcome, defined as a modified Rankin Scale score of 0–3, and health-related quality-of-life assessed using the Euro-QoL 5-Dimension 5-Level questionnaire on domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.

Results: Of the 1479 patients included in the main manuscript primary analyses, three were lost to follow-up for 1-year survival. At 1 year, 82 patients (11%) in the intraosseous group and 68 patients (9%) in the intravenous group were alive (risk ratio 1.24; 95% confidence interval 0.91–1.67). Survival with a favourable neurological outcome was observed in 76 patients (10%) and 61 patients (8%), respectively (risk ratio 1.28; 95% confidence interval 0.93–1.77). Among survivors, the mean EQ-5D-5L numeric score was 83 in the intraosseous group and 76 in the intravenous group (mean difference 7; 95% confidence interval 1–13).

Conclusion: Long-term outcomes were similar between patients who received initial intraosseous versus intravenous vascular access during adult out-of-hospital cardiac arrest. These findings do not support a difference in patient outcomes between the two vascular access strategies.

Trial registration: EU Clinical Trials number 2022-500744-38-00; ClinicalTrials.gov number NCT05205031.

Keywords: Cardiac arrest, Advanced life support, Vascular access, Clinical trial

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Introduction

Out-of-hospital cardiac arrest is a frequent medical emergency and is associated with high mortality.[1] Establishing vascular access during advanced life support is necessary to administer recommended pharmacologic treatments.[2] In 2020, the International Liaison Committee on Resuscitation found very low certainty of evidence that intraosseous as compared to peripheral venous drug administration resulted in improved patient outcomes.[3] Meanwhile, both intraosseous and intravenous routes were routinely used in clinical practice.[4]

The Intravenous versus Intraosseous Vascular Access for Out-of-Hospital Cardiac Arrest (IVIO) trial was conducted to compare the effectiveness of the two approaches. The trial's main results demonstrated no difference between intraosseous and intravenous access in return of spontaneous circulation, survival, or survival with a favourable neurological outcome at 30 or 90 days.[5]

The IVIO protocol prespecified follow-up at 6 months and 1 year.[6] This manuscript presents the long-term outcomes of survival, survival with a favourable neurological outcome, and health-related quality-of-life in patients enrolled in the IVIO trial.

Methods

Trial design and oversight

The IVIO trial was an investigator-initiated, randomised, parallel-group, superiority trial comparing initial attempts at intraosseous or intravenous vascular access during adult out-of-hospital cardiac arrest. The trial was approved by the relevant regulatory authorities and ethics committee. Procedures for consent followed relevant European[7] and Danish[8] legislations governing emergency research. Further details are provided in the published protocol and primary manuscript.[5,6]

Patients

Patients were included nationally in Denmark if they were 18 years of age or older, had a non-traumatic out-of-hospital cardiac arrest, and vascular access was indicated during resuscitation. Exclusion criteria were functioning vascular access at the time of possible enrolment, traumatic cardiac arrest, and prior inclusion in the trial. Eligible patients were randomised on scene by the treating clinician.

Randomisation, intervention, and blinding

Patients were allocated 1:1 to initial intraosseous or intravenous vascular access using sealed, opaque envelopes containing the assigned access method. Those randomised to the intraosseous group were further randomised 1:1 to either initial tibial or humeral access. The intervention consisted of attempting the allocated method for up to two attempts. If vascular access was not obtained, further attempts were at the discretion of the treating clinician.

Due to the nature of the intervention clinicians were aware of the allocation after randomisation. Neither patients nor their relatives were informed of the allocation. All follow-up outcome evaluations were performed by assessors who were blinded to the allocation.

Outcomes

This manuscript reports the long-term outcomes assessed at 6 months and at 1 year, i.e., survival, survival with a favourable neurological outcome, and health-related quality of life. Neurological outcome was evaluated using the modified Rankin Scale (mRS), with a score of 0 to 3 classified as favourable.[9] Health-related quality of life was assessed using the EuroQol 5-Dimension 5-Levels (EQ-5D-5L) questionnaire,[10] reported both as the patient-rated numeric score and an indexed value based on responses within five domains and on Danish population weights.[11] The five domains are mobility, self-care, usual activities, pain/discomfort, and anxiety/depression and levels range from "no problems" to "extreme problems" within each domain. The numeric score ranges from 0 to 100, where higher values reflect better perceived health status, while the indexed score may take on values below zero. Patients who died before a scheduled follow-up were assigned an mRS score of 6, and only survivors were included in analyses of health-related quality of life. Both the mRS-score and the EQ-5D-5L are recommended assessment tools by the Core Outcome Set for Cardiac Arrest initiative.[12] Follow-up interviews were conducted primarily by telephone or, whenever logistically possible, in person. Information was obtained from patients or, when necessary, from relatives or clinical staff.

Statistical analysis

All analyses followed a prespecified modified intention-to-treat approach including all patients who, at the time of randomisation, met all inclusion criteria and no exclusion criteria. Binary outcomes were summarised as counts and percentages. Between-group differences were expressed as both risk ratios and risk differences with 95% confidence intervals (CI) calculated using the methods described by Miettinen and Nurminen.[13] Continuous outcomes were summarised as means with standard deviations and compared using generalised linear models with robust standard errors to obtain mean differences and 95% CIs. The statistical analysis plan predefined a hierarchical approach for calculating *p*-values,[6] and as the primary outcome, reported previously, was not statistically significant,[5] the current manuscript does not report any p-values. All statistical analyses were conducted using Stata version 18.5 (StataCorp LLC).

Results

Patient characteristics

A total of 1479 patients, included from March 1, 2022 to May 5, 2024, were eligible for the main manuscript's primary analyses, with 731 assigned to initial intraosseous access and 748 to intravenous access. At 1 year-follow-up, two patients in the intraosseous group and one in the intravenous group were lost to follow-up. Baseline clinical and cardiac arrest characteristics have been reported previously and were comparable between groups.[5] The mean age was

69 (standard deviation: 14) years, 70% were male, 81% of cardiac arrests occurred at home, and 76% presented with an initial non-shockable rhythm.

Outcomes

A flow chart of screening, randomization, adherence to the intervention, and loss to follow-up is demonstrated in Fig. 1. Successful vas-

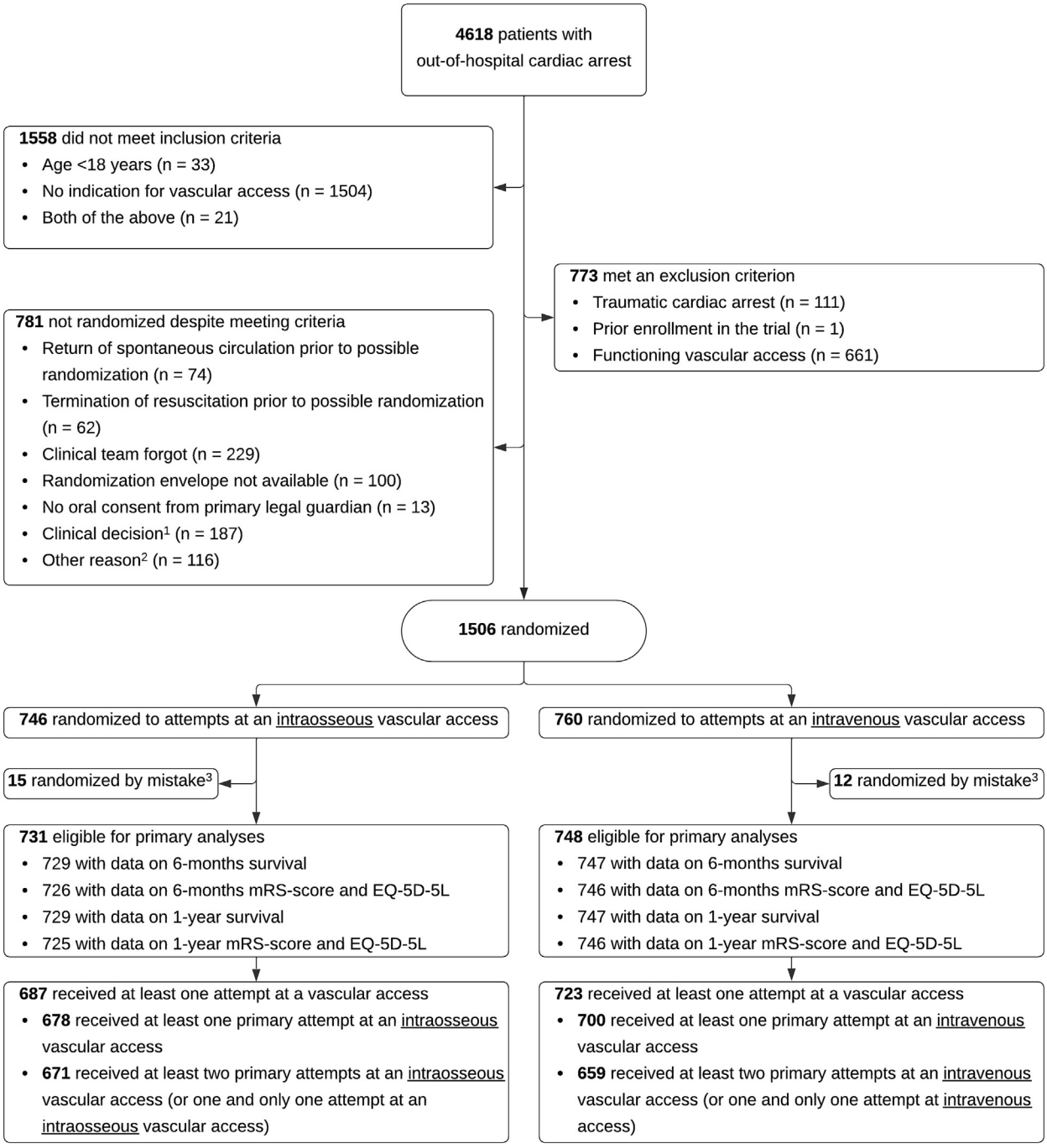

Fig. 1 – Screening, randomization, loss to follow-up, and adherence to the intervention.

EQ-5D-5L = EuroQol 5 Dimension 5 Levels, mRS = modified Rankin scale.

[1]Clinical decisions include: On-site clinician prioritised a specific type of vascular access, trial-participating personnel were prioritised to other tasks, and physical environment compromised placement of one of the interventions.

[2]Other reasons include: No trial-participating personnel attended the cardiac arrest, misunderstanding regarding the trial protocol, and miscommunication between on-site personnel.

[3]Post-randomization exclusions were predefined in the protocol and occurred if the patient, at the time of randomization, did not meet the inclusion criteria or met an exclusion criterion. For the intraosseous (IO) and intravenous (IV) groups, the reasons were as follows: Not in cardiac arrest at the time of randomization (IO: $n = 2$, IV: $n = 1$), age 17 years at the time of cardiac arrest (IV: $n = 2$), traumatic cardiac arrest (IO: $n = 4$, IV: $n = 4$), prior enrollment in the trial (IV: $n = 1$), and functioning vascular access (IO: $n = 9$, IV: $n = 4$).

cular access within two attempts occurred in 669 patients (92%) allocated to intraosseous access and 595 patients (80%) allocated to intravenous access. Outcomes regarding allocation of tibial vs. humeral access within the intraosseous group have been presented elsewhere.[5] Outcomes at 6 months and 1 year are presented in Tables 1 and 2, and survival over time is shown in Fig. 2.

At 1 year, 82 patients (11%) in the intraosseous group and 68 (9%) in the intravenous group were alive (risk ratio 1.24; 95% CI 0.91–1.67). A favourable neurological outcome was present in 76 patients (10%) in the intraosseous group and 61 (8%) in the intravenous group (risk ratio 1.28; 95% CI 0.93–1.77).

Among survivors, 1-year health-related quality of life assessments indicated a modest but uncertain difference between groups. The mean EQ-5D-5L numeric score was 83 in the intraosseous group and 76 in the intravenous group (mean difference 7; 95% CI 1–13).

Discussion

The long-term outcomes followed the pattern observed in the 30- and 90-day outcomes,[5] with estimates for survival, survival with a favourable neurological outcome, and health-related quality of life closely aligned between the two vascular access strategies. Although point estimates favoured intraosseous access, confidence intervals were imprecise and generally encompassed the possibility of no effect.

The stability of survival, survival with a favourable neurological outcome, and health-related quality of life after 90-day follow-up mirrors observations from previous long-term assessments of intra-arrest interventions intended to enhance return of spontaneous circulation.[14–16] In those trials, early outcome patterns were largely maintained at later follow-up, suggesting that any treatment effects typically manifest during or shortly after resuscitation and are sustained after the first few months. Consequently, extending follow-up beyond 90 days may add limited incremental information when evaluating such interventions. Long-term outcomes are still pending from a major British trial, which included 6082 patients with similar eligibility criteria to the current trial.[17]

The finding indicating that 1-year health-related quality of life is higher in patients with an intraosseous as compared to an intravenous vascular access strategy during the cardiac arrest should be interpreted with caution. Confidence intervals have not been adjusted for multiplicity, increasing the risk of a type 1 error. Additionally, time to return of spontaneous circulation was similar between the two groups,[5] why a clinical causal pathway to better health-related quality of life would have to be through other mechanisms.

Limitations

The limitations presented in the main manuscript also apply to the long-term follow-up.[5] The number of patients with long-term survival was low resulting in wide confidence intervals, and a type 2 error cannot be ruled out.

Table 1 – Outcomes according to allocation.

	Intraosseous (*n* = 731)	Intravenous (*n* = 748)	Risk ratio (95% CI)	Difference* (95% CI)
6-months outcomes**				
Survival	82 (11)	69 (9)	1.22 (0.90–1.65)	2.0 (−1.1 to 5.1)
Favourable neurologic outcome (mRS 0–3)	77 (11)	63 (8)	1.26 (0.92–1.72)	2.2 (−0.8 to 5.2)
EQ-5D-5L – assessed by the patient***	81 (15)	78 (18)	–	3 (−2 to 8)
EQ-5D-5L – indexed value***	89 (13)	84 (24)	–	5 (−1 to 11)
1-year outcomes****				
Survival	82 (11)	68 (9)	1.24 (0.91–1.67)	2.1 (−0.9 to 5.3)
Favourable neurologic outcome (mRS 0–3)	76 (10)	61 (8)	1.28 (0.93–1.77)	2.3 (−0.7 to 5.3)
EQ-5D-5L – assessed by the patient***	83 (14)	76 (21)	–	7 (1–13)
EQ-5D-5L – indexed value***	89 (18)	80 (28)	–	9 (1–17)

Continuous variables are presented as means with standard deviations and categorical variables as numbers and percentages.

EQ-5D-5L results are reported both as the patient-assessed numeric value and as the indexed value based on Danish data. The numeric value is reported on a scale from 0 to 100 with higher scores indicating a better health-related quality of life. The indexed value can be negative.

The widths of the 95% confidence intervals have not been adjusted for multiplicity and the intervals should not be used in place of hypothesis testing.

CI = confidence interval, EQ-5D-5L = EuroQol 5 Dimension 5 Levels, mRS = modified Rankin scale.

* Risk difference in percentage points for binary outcomes and mean difference for continuous outcomes.

** Loss-to-follow for 6-months outcomes: Survival = 2/731 (0.3%) for intraosseous, 1/748 (0.1%) for intravenous; favourable neurologic outcome and EQ-5D-5L = 5/731 (0.7%) for intraosseous, 2/748 (0.3%) for intravenous.

*** Health-related quality of life outcomes (EQ-5D-5L) only include patients that survived to that time point.

**** Loss-to-follow for 1-year outcomes: Survival = 2/731 (0.3%) for intraosseous, 1/748 (0.1%) for intravenous; favourable neurologic outcome and EQ-5D-5L = 6/731 (0.8%) for intraosseous, 2/748 (0.3%) for intravenous.

Table 2 – Favourable neurological outcome and EQ-5D-5L subcategories in survivors.

	6 months		1 year	
	Intraosseous (*n* = 79)*	Intravenous (*n* = 68)*	Intraosseous (*n* = 78)**	Intravenous (*n* = 67)**
Favourable neurological (mRS 0–3) outcome in survivors	77 (97)	63 (93)	76 (97)	61 (91)
EQ-5D-5L subcategories				
Mobility				
No problems	57 (72)	44 (65)	58 (74)	39 (58)
Slight problems	14 (18)	13 (19)	11 (14)	10 (15)
Moderate problems	5 (6)	4 (6)	8 (10)	9 (13)
Severe problems	2 (3)	3 (4)	1 (1)	4 (6)
Extreme problems	1 (1)	4 (6)	0 (0)	5 (7)
Self-care				
No problems	69 (87)	58 (85)	69 (88)	53 (79)
Slight problems	6 (8)	4 (6)	5 (6)	3 (4)
Moderate problems	3 (4)	0 (0)	3 (4)	4 (6)
Severe problems	0 (0)	1 (1)	0 (0)	1 (1)
Extreme problems	1 (1)	5 (7)	1 (1)	6 (9)
Usual activities				
No problems	41 (52)	33 (49)	44 (56)	25 (37)
Slight problems	20 (25)	13 (19)	11 (14)	18 (27)
Moderate problems	11 (14)	12 (18)	16 (21)	10 (15)
Severe problems	2 (3)	2 (3)	2 (3)	5 (7)
Extreme problems	5 (6)	8 (12)	5 (6)	9 (13)
Pain and discomfort				
No problems	47 (59)	42 (62)	50 (64)	40 (60)
Slight problems	25 (32)	21 (31)	21 (27)	19 (28)
Moderate problems	6 (8)	4 (6)	5 (6)	4 (6)
Severe problems	1 (1)	1 (1)	1 (1)	3 (4)
Extreme problems	0 (0)	0 (0)	1 (1)	1 (1)
Anxiety and depression				
No problems	58 (73)	46 (68)	60 (77)	45 (67)

(*continued on next page*)

Table 2 (continued)

	6 months		1 year	
	Intraosseous (*n* = 79)*	Intravenous (*n* = 68)*	Intraosseous (*n* = 78)**	Intravenous (*n* = 67)**
Slight problems	15 (19)	13 (19)	12 (15)	15 (22)
Moderate problems	6 (8)	8 (12)	5 (6)	6 (9)
Severe problems	0 (0)	0 (0)	0 (0)	1 (1)
Extreme problems	0 (0)	1 (1)	1 (1)	0 (0)

Categorical variables are presented as counts and percentages.

Outcomes are only presented for survivors at the given time-point. EQ-5D-5L subcategories are patient-assessed with five levels for five dimensions of health-related quality of life.

EQ-5D-5L = EuroQol 5 Dimension 5 Levels, mRS = modified Rankin scale.

* Loss to follow-up for favourable neurological outcome and health-related quality of life outcomes was at 6 months: 5/84 (6%) for intraosseous, 2/70 (3%) for intravenous. For completed 6-months follow-up the responders were as follows: Patient (*n* = 75 [95%] for intraosseous, *n* = 62 [91%] for intravenous), closest relative (*n* = 4 [5%] for intraosseous, *n* = 5 [7%] for intravenous), and clinical personnel (*n* = 0 [0%] for intraosseous, *n* = 1 [1%] for intravenous).

** Loss to follow-up for favourable neurological outcome and health-related quality of life outcomes was at 1 year: 6/84 (7%) for intraosseous, 2/69 (3%) for intravenous. For completed 1-year follow-up the responders were as follows: Patient (*n* = 74 [95%] for intraosseous, *n* = 61 [91%] for intravenous), closest relative (*n* = 4 [5%] for intraosseous, *n* = 5 [7%] for intravenous), and clinical personnel (*n* = 0 [0%] for intraosseous, *n* = 1 [1%] for intravenous).

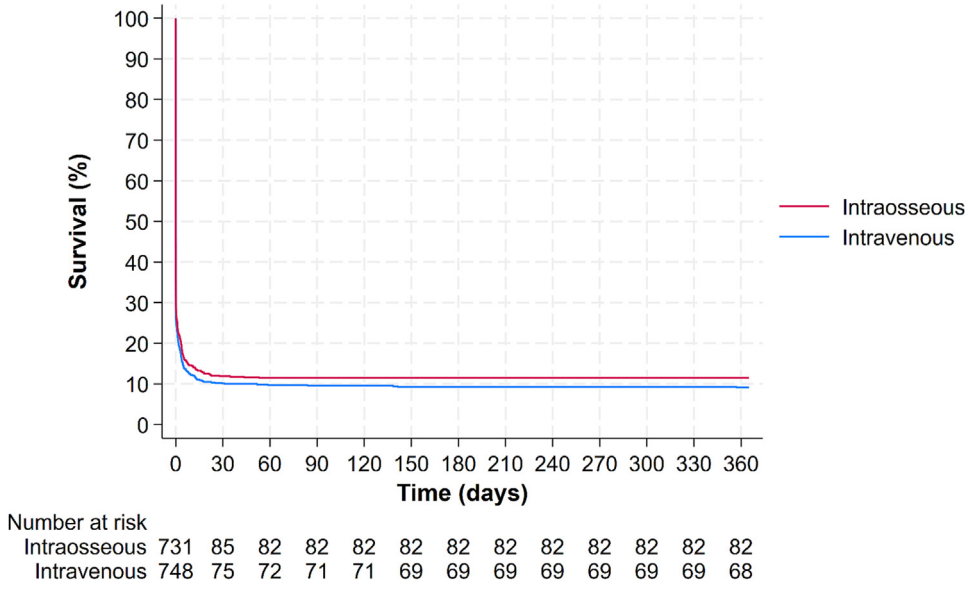

Fig. 2 – Survival over time.
Three patients were lost to follow-up for survival at 1 year. One patient was censored on day 3 (intravenous) due to patient decline of consent, and two patients (both intraosseous) were censored on day 14, one due to patient decline of consent and one was a foreign citizen who left the country after hospital discharge.

Conclusion

In this randomised clinical trial of vascular access during out-of-hospital cardiac arrest, initial intraosseous and intravenous strategies resulted in similar patient outcomes at 1 year. Overall, these findings indicate that the choice of initial vascular access route during resuscitation does not influence long-term patient outcomes.

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The funding agencies had no role in the design and conduct of the trial; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; or the decision to submit the manuscript for publication.

Data access, responsibility, and analysis

Drs. Fink Vallentin and Andersen had full access to all of the data in the trial and take responsibility for the integrity of the data and the accuracy of the data analysis.

CRediT authorship contribution statement

Mikael Fink Vallentin: Writing – review & editing, Writing – original draft, Visualization, Validation, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Mathias J. Holmberg:** Writing – review & editing, Resources, Investigation. **Asger Granfeldt:** Writing – review & editing, Resources, Project administration, Methodology, Investigation, Conceptualization. **Thomas Lass Klitgaard:** Writing – review & editing, Resources, Methodology, Investigation, Conceptualization. **Søren Mikkelsen:** Writing – review & editing, Resources, Methodology, Investigation, Conceptualization. **Fredrik Folke:** Writing – review & editing, Resources, Methodology, Investigation, Conceptualization. **Helle Collatz Christensen:** Writing – review & editing, Resources, Methodology, Investigation, Conceptualization. **Amalie Ling Povlsen:** Writing – review & editing, Resources, Investigation. **Alberthe Hjort Petersen:** Writing – review & editing, Resources, Investigation. **Sofie Winther:** Writing – review & editing, Resources, Investigation. **Lea Wildt Frilund:** Writing – review & editing, Resources, Investigation. **Carsten Meilandt:** Writing – review & editing, Resources, Methodology, Investigation, Conceptualization. **Kristian Blumensaadt Winther:** Writing – review & editing, Resources, Methodology, Investigation, Conceptualization. **Allan Bach:** Writing – review & editing, Resources, Methodology, Investigation, Conceptualization. **Thomas H. Dissing:** Writing – review & editing, Resources, Methodology, Investigation, Conceptualization. **Christian Juhl Terkelsen:** Writing – review & editing, Resources, Methodology, Investigation, Conceptualization. **Steffen Christensen:** Writing – review & editing, Resources, Methodology, Investigation, Conceptualization. **Line Kirkegaard Rasmussen:** Writing – review & editing, Resources, Investigation. **Lone Riis Mortensen:** Writing – review & editing, Resources, Investigation. **Thomas Elkmann:** Writing – review & editing, Resources, Methodology. **Anders Gunnar Nielsen:** Writing – review & editing, Resources, Investigation. **Charlotte Runge:** Writing – review & editing, Resources, Investigation. **Elise Klæstrup:** Writing – review & editing, Resources, Investigation. **Jimmy Højberg Holm:** Writing – review & editing, Resources, Investigation. **Mikkel Bak:** Writing – review & editing, Resources, Investigation. **Lars-Gustav Rahbek Nielsen:** Writing – review & editing, Resources, Investigation. **Mette Pedersen:** Writing – review & editing, Resources, Investigation. **Gunhild Kjærgaard-Andersen:** Writing – review & editing, Resources, Investigation. **Peter Martin Hansen:** Writing – review & editing, Resources, Investigation. **Anne Craveiro Brøchner:** Writing – review & editing, Resources, Investigation. **Erika Frischknecht Christensen:** Writing – review & editing, Resources, Investigation. **Frederik Mølgaard Nielsen:** Writing – review & editing, Resources, Investigation. **Christian Gade Nissen:** Writing – review & editing, Resources, Investigation. **Jeppe Waldstrøm Bjørn:** Writing – review & editing, Resources, Investigation. **Peter Burholt:** Writing – review & editing, Resources, Investigation. **Laust E.R. Obling:** . **Sarah Louise Duus Holle:** Writing – review & editing, Resources, Investigation. **Lene Russell:** Writing – review & editing, Resources, Investigation. **Henrik Alstrøm:** Writing – review & editing, Resources, Investigation. **Søren Hestad:** Writing – review & editing, Resources, Investigation. **Jens Ulrik Hove Buciek:** Writing – review & editing, Resources, Investigation. **Karina Jakobsen:** Writing – review & editing, Resources, Investigation. **Mette Krag:** Writing – review & editing, Resources, Investigation. **Michael Sandgaard:** Writing – review & editing, Resources, Investigation. **Birthe Sindberg:** Writing – review & editing, Resources, Investigation. **Lars W. Andersen:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: 'Mikael Fink Vallentin reports financial support was provided by Health Research Foundation of Central Denmark Region. Lars W. Andersen reports financial support was provided by Novo Nordisk Foundation. Lars W. Andersen reports financial support was provided by TrygFonden. Lars W. Andersen reports financial support was provided by Independent Research Fund Denmark. Lars W. Andersen reports financial support was provided by Cabinetmaker Sophus Jacobsen and wife Astrid Jacobsen's Foundation. Lars W. Andersen is an editorial board member of both the Resuscitation and Resuscitation Plus Journals'.

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